Remarks

A. Status of the Claims

Claims 14-29 were pending at the time of the Action. Claims 14, 23, 24, and 25 have been amended. Claims 15, 16, 18, 19, 21, 22 and 26-29 have been cancelled without prejudice or disclaimer. Support for "full length" SEQ ID NO:1 in claim 14, can be found throughout the disclosure as well as in the Sequence Listing. Support for the phrase including "the presence of said nucleic acid in a sample of a subject indicates that the subject has an increased risk of idiopathic generalized epilepsy" in claim 24 can be found in the specification, for example, at pages 52 and 54-59 (Examples 3, 6 and 7). Support for the phrase "an A to T mutation at position 828 of SEQ ID NO:1" in claim 25(a), can be found in the specification, for example from page 55, line 3 to page 56, line 6, at page 27, lines 14 to 17 and in the Sequence Listing. Support for the phrase "an A to C mutation at position 3978 of SEQ ID NO:1" in claim 25(b), can be found in the specification, for example at page 52, lines 3 to 9, as well as in Figure 3 and in the Sequence Listing. Support for the phrase "a C to A mutation at position 5582 of SEQ ID NO:1" in claim 25(c), can be found in the specification, for example at page 52, lines 15-19 as well as in Figure 3 and in the Sequence Listing.

Claims 14, 17, 20 and 23-25 are pending.

B. Information Disclosure Statements

1. Information Disclosure Statement Filed October 16, 2006

Reference C77: Reference C77 has been crossed off by the Examiner because it was incomplete. Since AF035685 and AF035686 relate both to SCN3A sequences and not to the elected SCN1A sequences, these sequences are considered immaterial to the patenting of the instant claims and are thus not resubmitted.

Reference C78: Applicants acknowledge that reference C78 was a duplicate that had already been considered by the Examiner.

2. Information Disclosure Statement Filed January 29, 2007

Reference C79: As requested by the Examiner, relevant pages of reference C79 are being submitted in a Supplemental Information Disclosure Statement concurrently with this response. More particularly, pages 1-12, 38-50 and 80-83 are being submitted together with the table of contents of the Journal.

Reference C81: Partial reference C81 was received from Examiner Sue Liu in an Office Action dated November 11, 2006, in parent application No. 10/664,603. More particularly, the blast result submitted as reference C81 was provided by the Examiner with regard to comparison of SCN3A sequences (SEQ ID NOs: 72 and 73 of the instant sequence listing), which were considered as not sharing significant sequence similarity. Since the present application relates to SCN1A sequences, this reference is not resubmitted.

C. Maintained Rejections and Objections

1. Claims 14-29 Are Enabled by the Specification

Claims 14-29 are rejected under 35 U.S.C. § 112, first paragraph, as not complying with the enablement requirement. Specifically, the claims are rejected based on an alleged insufficient enablement for all complements, fragments, functional derivatives or allelic variants encompassed by claims 14-16 or for all nucleic acids, which have only 119 contiguous bases of SEQ ID NO:1 in claim 29.

Applicants disagree as the claims are enabled by the specification. However, in an effort to further the prosecution of this case and secure prompt allowance, claims 14 has been revised and claims 15, 16, and 29 have been canceled. Claim 14 is now directed to a nucleic acid

sequence selected from the group consisting of (a) the nucleic acid of SEQ ID NO:1; (b) a full length complement of (a); and (c) a nucleic acid sequence having at least 95% identity to the full length nucleic acid sequence in (a) or (b). In view of the above, the enablement rejection is moot and should be withdrawn.

For the record, Applicants note that the rejected claims are enabled as set forth in the response dated December 22, 2006. Applicants reserve the right to pursue fragments, functional derivatives and allelic variants in further applications.

2. Claims 14-28 Satisfy the Written Description Requirement

Claims 14-28 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Action alleges that the description of the application would not reasonably convey to one of skill in the art that the Applicants had possession of nucleic acid sequences for any fragment, functional derivative, or allelic variant of the claimed sequences.

Applicants disagree, as the claims satisfy the written description requirement. However, in an effort to further the prosecution of this case and secure prompt allowance, claim 14 is now directed to nucleic acids having at least 95% identity to the full length of SEQ ID NO:1, and claims 15, 16, 18, 19, 21 and 22 have been canceled. In view of the above, the written description rejection is moot and should be withdrawn.

For the record, Applicants note that the rejected claims satisfy the written description requirement as set forth in the response dated December 22, 2006. Applicants reserve the right to pursue fragments, functional derivatives and allelic variants in further applications.

3. Claims 14-24 and 29 Are Not Anticipated by the Mandel and Noda References

Claims 14-24 and 29 have been rejected as being allegedly "anticipated by Mandel (WO 96/14077...), as evidenced by Mandel (US Patent 6,110,672)" under 35 U.S.C. § 102. Further, Claims 14-19, 23-24 and 29 have been rejected as being allegedly "anticipated by Noda (1986, Nature 320: 188-192), as evidenced by a sequence alignment for NCBI Accession Number X03638."

Applicants disagree, as the cited references fail to disclose every element of the rejected claims. However, in an effort to further the prosecution of this case and secure prompt allowance, claim 14 is currently directed to SEQ ID NO:1, a full-length complement thereof, or a nucleic acid sequence with at least 95% identity to the full length of either of the above. None of these sequences are disclosed in Mandel and Noda. Therefore, Applicants request that these anticipation rejections be withdrawn. *See In re Bond*, 910 F.2d 831, 832 (Fed. Cir. 1990) ("For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be identically shown in a single reference. These elements must be arranged as in the claim under review....").

4. Claims 14-24 and 29 Are Not Rendered Obvious Over Noda in view of Wang

Claims 14-24 and 29 have been rejected as being allegedly unpatentable over Noda (1986, Nature 320: 188-192) in view of Wang (1997, J. Clin Invest. 99: 1714-1720) under 35 U.S.C. § 103.

Applicants disagree and reminds the examiner that in order in order "to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art." MPEP § 2143.03. Such a showing cannot be made. For instance, for the reasons set forth above and incorporated into this section, Noda fails to disclose or suggest the nucleic

acid of claim 14. Similarly, while Wang teaches transfecting vectors comprising nucleic acids encoding sodium channels into cells, it also fails to disclose or suggest the nucleic acids of claim 14. Therefore, the combination of Noda and Wang fails to disclose or suggest every element of the claimed invention.

Applicants request that the obviousness rejection be withdrawn.

D. Rejections and Objections Necessitated by Amendment

1. Claims 25-29 Satisfy the Written Description Requirement

Claims 25-29 have been rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Action first alleges that the description of the application would not reasonably convey to one of skill in the art that the Applicants had possession of the three specific mutations and combination thereof, recited in claims 25 parts (a)-(d) as well as in claims 26-28, which are considered as new matter.

Applicants respectfully submit that one must not place undue emphasis on the presence or absence of literal support in the specification for the claim language. The test is whether the disclosure of the application as originally filed "reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter" *In re Kaslow*, 707 F.2d 1366 (Fed. Cir. 1983). Applicants submit that support for the position of the three mutations listed in claim 25(a) to (c) may be inferred from the disclosure as originally filed.

More particularly, the mutation in part (a) of claim 25 (position 828 of SEQ ID NO:1) corresponds to a mutation at position 188 of the amino acid sequence of SCN1A, as described from page 55, line 3 to page 56, line 6. Having disclosed the nucleic acid (cDNA) and protein sequence of SCN1A (corresponding to SEQ ID NOS:1 and 3. See page 27, lines 14 to 17 and the Sequence Listing) and having disclosed that a mutation was found at amino acid position 188

of SCN1A (see page 55, lines 3-25), one skilled in the art, cognizant of the genetic code, can easily locate the corresponding nucleotide position in SEQ ID NO:1. Thus, the specification as originally filed supports " an A to T mutation at position 828 of SEQ ID NO:1".

Similarly, the A to C mutation at position 3978 of SEQ ID NO:1 described in part (b) of claim 25, is supported by the disclosure at page 52, lines 3-9 as well as in Figure 3 (mutation at position 1238 of SEQ ID NO:3 or mutation in the following nucleotide sequence: GCA TTT GAC GAT ATA). Likewise, the C to A mutation at position 5582 of SEQ ID NO:1 described in part (c) of claim 25, is supported by the disclosure at page 52, lines 15-19 as well as in Figure 3 (mutation at position 1773 of SEQ ID NO:3 or mutation in the following nucleotide sequence: ATC ATA TmC TTC CTG).

Thus, having disclosed not only the SCN1A cDNA and protein sequences, but also the portions of the nucleotide sequence around the identified mutations (page 52, line 5), one skilled in the art can easily identify the corresponding nucleotide positions in SEQ ID NO:1 as being 3978 and 5582. Accordingly, the specification as originally filed supports an A to C and C to A mutations at positions 828 and 5582 of SEQ ID NO:1.

In order to expedite the prosecution of the instant application, Applicants have deleted part (d) from claim 25 without prejudice or disclaimer. For the record however, Applicants submit that support for claim 25, part (d), relating to combinations of the mutations listed in part (a) to (c), can be found at page 21, line 15 and at page 22, lines 2-5. In addition, given that the individually described mutations were discovered in the SCN1A gene of patients suffering from epilepsy (and are thus readily found in nature), one skilled in the art can easily expect to find a combination of the above-described mutations in nature, based solely on the possibility that two parents, each carrying one of the above-described mutations, could give birth to a child carrying

two mutations. Thus, the combination of mutations described in claim 25, part (d) are not any combination of mutations but combinations that are expected to be found in nature based on Applicants' disclosure.

For at least the above reasons, Applicants request that the written description rejection be withdrawn.

2. Claims 14-15, 17-18, 20-21, and 23-28 Are Definite

Claims 14-15, 17-18, 20-21 and 23-28 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. For instance, claim 14 has been rejected for being "confusing," and claim 24 allegedly includes a "relative term which renders the claim indefinite."

Applicants disagree, as a person of ordinary skill in the art would understand the full scope of the claims when read alone, or in light of the specification. However, in an effort to further the prosecution of this case and secure a prompt allowance, claims 14 and 24 have been revised to address the examiner's concern. Further, Claims 15, 18, 19, 21, and 22 have been canceled.

Applicants request that the indefiniteness rejections be withdrawn.

3. Priority of Applicants' Claimed Invention

It is alleged that the Applicants have not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. § 120 and 119(e). More particularly, it is alleged that the prior-filed applications 60/167623 and 09/718355 do not support mutations at positions 828, 3978 and 5582 (formerly recited as 5581), as well as combinations of these mutations recited in claim 25 part (a) to (d).

Applicants disagree for at least the following reasons: (1) the support identified in the instant specification regarding mutations at position 828, 3978 and 5582 (see above); (2) the deletion of part (d) from claim 25 without prejudice or disclaimer; (3) the fact that these portions

of the specification are found in the two prior-filed applications; and (4) the cancellation of claims 26-29.

Therefore, it is submitted that claim 25 is entitled to the earliest priority date of application no 60/167623, namely November 26, 1999.

4. Claims 14, 16, 23, and 29 Are Not Anticipated by the Stratagene Catalog and the Furness References

Claims 14 and 29 have been rejected as being allegedly anticipated by the Stratagene Catalog (1991, p.66) under 35 U.S.C. § 102(b). In addition, Claims 14, 16, 23 and 29 are rejected as being allegedly anticipated by Furness (U.S. Patent 6,673,549, issued January 6, 2004, filing date October 12, 2001 and priority date of October 12, 2001).

Applicants disagree. However, in an effort to further the prosecution and secure prompt allowance, claim 14 has been revised to concern SEQ ID NO:1, full-length complement of SEQ ID NO:1, and nucleic acid sequences having at least 95% identity to full-length SEQ ID NO:1 or full-length complement of SEQ ID NO:1. These sequences are not disclosed or suggested by the Stratagene Catalog and the Furness references. In addition, Furness is not a citable reference in view of the priority date of the present application.

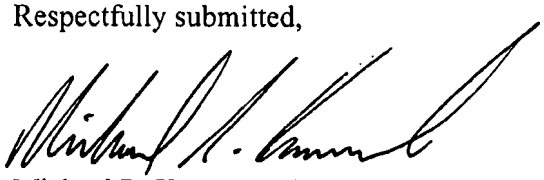
Applicants request that the anticipation rejections be withdrawn.

E. Conclusion

Applicants believe that the present document is a full and complete response to the Action dated March 30, 2007. The present case is in condition for allowance, and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned Attorney at 512.536.3020 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,



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